Notice of Allowability	Application No.	Applicant(s)	
	09/580,018	SCHENK ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *22 September 2003*.
2. ☒ The allowed claim(s) is/are *1,6-9,11-16,19-25,27-32,35-41,44,69-71 and 76*.
3. ☒ The drawings filed on *22 September 2003* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
5☒ Information Disclosure Statements (PTO-1449), Paper No. ____.
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
2☐ Notice of Informal Patent Application (PTO-152)
4☐ Interview Summary (PTO-413), Paper No.____ .
6☒ Examiner's Amendment/Comment
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment/Response filed 22 September 2003 has been received and entered in full. Claims 1 and 46 have been amended. Claims 10, 26, 42, and 43 have been cancelled. Claims 69-75 have been added. Claims remain withdrawn from consideration.

2. The Declaration under MPEP §2406.02 filed on 22 September 2003 has been entered.

Withdrawn Objections And/Or Rejections

3. All previous Rejections and Objections not made herein are withdrawn.

Terminal Disclaimer

4. The terminal disclaimer filed on 14 November 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 09/724961 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the Claims:

Claim 1 (Currently Amended) A method of prophylactically or therapeutically treating Alzheimer's disease ~~a disease associated with amyloid deposits of Aβ in the brain of a patient~~, comprising administering to the patient an effective dosage of a pharmaceutical composition comprising a human, humanized, or chimeric antibody that specifically binds to an epitope within Aβ1-7, and hereby prophylactically or therapeutically treating the patient.

Claims 2-5 (Cancelled)

Claim 6 (Original) The method of claim 1, wherein the antibody is of human isotype IgG1.

Claim 7 (Currently Amended) The method of any one of the preceding claims, wherein the patient is human.

Claim 8 (Original) The method of claim 1, wherein the antibody specifically binds to an epitope within residues 1-6 of Aβ.

Claim 9 (Original) The method of claim 1, wherein the antibody specifically binds to an epitope within residues 1-5 of Aβ.

Claim 10 (Cancelled)

Claim 11 (Original) The method of claim 1, wherein the antibody specifically binds to an epitope within residues 3-7 of Aβ.

Claim 12 (Original) The method of claim 1, wherein the antibody specifically binds to an epitope within residues 1-3 of Aβ.

Claim 13 (Original) The method of claim 1, wherein the antibody specifically binds to an epitope within residues 1-4 of Aβ.

Claim 14 (Original) The method of claim 1, wherein after administration the antibody binds to an amyloid deposit in the patient and induces a clearing response against the amyloid deposit.

Claim 15 (Original) The method of claim 14, wherein the clearing response is an Fc receptor mediated phagocytosis response.

Claim 16 (Original) The method of claim 15, further comprising monitoring the clearing response.

Claim 17 (Cancelled)

Claim 18 (Cancelled)

Claim 19 (Original) The method of claim 1, wherein the patient is asymptomatic.

Claim 20 (Original) The method of claim 1, wherein the patient is under 50.

Claim 21 (Original) The method of claim 1, wherein the patient has inherited risk factors indicating susceptibility to Alzheimer's disease.

Claim 22 (Original) The method of claim 1, wherein the patient has no known risk factors for Alzheimer's disease.

Claim 23 (Original) The method of claim 1, wherein the antibody is a human antibody.

Claim 24 (Original) The method of claim 1, wherein the antibody is a humanized antibody.

Claim 25 (Original) The method of claim 1, wherein the antibody is a chimeric antibody.

Claim 26 (Cancelled)

Claim 27 (Original) The method of claim 1, wherein the antibody is a polyclonal antibody.

Claim 28 (Original) The method of claim 1, wherein the antibody is a monoclonal antibody.

Claim 29 (Original) The method of claim 1, further comprising administering an effective dosage of at least one other antibody that binds to a different epitope of Aβ.

Claim 30 (Original) The method of claim 1, wherein the isotype of the antibody is IgG1 or IgG4.

Claim 31 (Original) The method of claim 1, wherein the isotype of the antibody is IgG2 or IgG3.

Claim 32 (Original) The method of claim 1, wherein the antibody comprises two copies of the same pair of light and heavy chains.

Claims 33-34 (Cancelled)

Claim 35 (Original) The method of claim 1, wherein the dosage of antibody is at least 1 mg/kg body weight of the patient.

Claim 36 (Original) The method of claim 1, wherein the dosage of antibody is at least 10 mg/kg body weight of the patient.

Claim 37 (Previously Amended) The method of claim 1, wherein the antibody is administered with a carrier.

Claim 38 (Currently Amended) The method of claims 1, wherein the antibody is a human antibody to Aβ prepared from B cells from a human immunized with an Aβ peptide.

Claim 39 (Original) The method of claim 38, wherein the human immunized with Aβ peptide is the patient.

Claim 40 (Original) The method of claim 1, wherein the antibody specifically binds to Aβ peptide without binding to full-length amyloid precursor protein (APP).

Claim 41 (Currently Amended) The method of claim 1, wherein the antibody is administered intraperitoneally, orally, subcutaneously, intranasally, intramuscularly, topically, or intravenously.

Claims 42-43 (Cancelled)

Claim 44 (Original) The method of claim 1, further comprising monitoring the patient for level of administered antibody in the blood of the patient.

Claims 45-68 (Cancelled)

Claim 69 (Previously Added) The method of claim 1, wherein the method further comprises monitoring a response to the administration of the antibody to the patient.

Claim 70 (Previously Added) The method of claim 1, wherein a single dosage of the antibody is administered on multiple occasions.

Claim 71 (Previously Added) The method of claim 70, wherein the single dosage is administered once every week, once per every two weeks, once a month, once every 3 to 6 months, or yearly.

Claims 72-75 (Cancelled)

Claim 76 (New-Claim 45 Re-interested) The method of claim 70 or 71 wherein the occasions occur over a period of at least six months.

6. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli (Reg. No. 42,397) on 14 November 2003.

In the Title:

PASSIVE IMMUNIZATION TREATMENT OF ALZHEIMER'S DISEASE

Summary

7. Claims **1, 6-9, 11-16, 19-25, 27-32, 35-41, 44, 69, 70, 71,** and **76** are hereby allowed.

8. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
December 1, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600